



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,209	11/08/2007	Jeffrey L. Southard	560252000700	2819
25226	7590	01/27/2010	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018				LI, RUIXIANG
ART UNIT		PAPER NUMBER		
1646				
MAIL DATE		DELIVERY MODE		
01/27/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/586,209	SOUTHARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-47 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ .                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ .   | 6) <input type="checkbox"/> Other: ____ .                         |

## **REQUIREMENT FOR UNITY OF INVENTION**

### **1. Restriction is required under 35 U.S.C. 121 and 372.**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-15 (in part), 16, 18-36 (in part), drawn to a method of treating heart failure in a patient, comprising delivering to said patient CGRP in an amount effective to provide symptomatic relief, wherein said CGPR is delivered to said patient as a controlled release composition.

II. Claims 1-15 (in part), 17, 18-36 (in part), drawn to a method of treating renal failure in a patient, comprising delivering to said patient CGRP in an amount effective to provide symptomatic relief, wherein said CGPR is delivered to said patient as a controlled release composition.

III. Claims 37-42, drawn to a method of preventing or reducing the risk of occurrence of myocardial infarction, comprising delivering to a human at risk of having a myocardial infarction a controlled release formulation of CGRP comprising an amount of CGRP effective to prevent or reduce the risk or occurrence of myocardial infarction.

IV. Claims 43-46, drawn to a kit comprising a first container comprising a controlled release formulation of CGRP.

- V. Claim 47, drawn to a method of counteracting ischemia due to myocardial infarction in a patient, comprising delivering to said patient an amount of CGRP effective to provide cardioprotection, wherein said CGPR is delivered to said patient as a controlled release composition.
2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Invention Groups I-V lack unity of invention because even though the inventions of these groups require the technical feature of a controlled release formulation of CGRP and using the formulation for treating heart failure or renal failure. This technical feature is not a special technical feature as it does not make a contribution over the prior art in view of EP 0845269 A2 (March 6, 1998). EP 0845269 A2 teaches a pharmaceutical composition comprising hCGRP and liposomes that can be administrated by intravenous infusion, oral, nasal mucosal spray in an amount of 0.1-10 pg hCGRP per kg body weight to treat hypertension and congestive heart failure of a human (see, e.g., Abstract). Therefore, the shared technical feature does not make a contribution over the prior art

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

***Species Election***

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of controlled release composition (five) are as listed in claims 2, 20, 24, 27, and 28; claims 32-36; and 38-42.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1, 31, and 36.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species listed above are not regarded as being of similar nature because each controlled release composition possess distinct physical-chemical features.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/  
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.  
January 22, 2010